PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 February 2001 (15.02.01)	
International application No. PCT/EP00/05852	**Applicant's or agent's file reference** FB/BM45395
International filing date (day/month/year) 23 June 2000 (23.06.00)	**Priority date** (day/month/year) 25 June 1999 (25.06.99)
Applicant THONNARD, Joelle	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   18 December 2000 (18.12.00)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Pascal Piriou
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

BM45398
FB

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PCT/ISA/220

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND SOMETIMES 204 - INVITATION TO COMMENT ON ABSTRACT

PROCEDURE:

Prepare CITATION front sheet – s:\admin\template\citation and attach to front of citations. ☑

***If Harlow originating case*: send copy Search Report to ~~HLW~~ attorney for subsequent filing in Harlow General File. Original to be filed on PCT file at NHC.** ☐

***If NHC originating case*: send original SR to Attorney** ☑

***If US originating case (being filed in Europe ~~because applicant~~ is European)*: send original SR to UK Attorney for file and send copy SR to US Attorney in Upper Merion. General files are *not* being created for US originating PCT applications.** ☐

DATABASE PROCEDURE:

If Form 204 is attached enter an OAC code with appropriate due date for reply ☐

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
SMITHKLINE BEECHAM PLC
Corporate Intellectual Property
Attn. PRIVETT, Kathryn Louise
Two New Horizons Court
Brentford
Middlesex TW8 9EP
UNITED KINGDOM

20 NOV 2000

	Date of mailing *(day/month/year)* 17/11/2000
Applicant's or agent's file reference FB/BM45395	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/EP 00/05852	International filing date *(day/month/year)* 23/06/2000
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A.	

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Mireille Claudepierre

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file referenc	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
FB/BM45395		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/05852	23/06/2000	25/06/1999
Applicant		
SMITHKLINE BEECHAM BIOLOGICALS S.A.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[X] contained in the international application in written form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[ ] the text is approved as submitted by the applicant.

[X] the text has been established by this Authority to read as follows:

BASB111 POLYPEPTIDE AND POLYNUCLEOTIDE FROM MORAXELLA CATHARRHALIS

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

[ ] as suggested by the applicant.

[X] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/05852

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/31 C07K14/21 A61K39/02 A61K39/395 A61K48/00
G01N33/569 C07K16/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C07K C12N A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 18323 A (ASTRA AB ;ALM RICHARD A (US); SMITH DOUGLAS (US)) 7 May 1998 (1998-05-07) SEQ ID NOs:19, 92 claims 1-65 ---	5-7,9, 15, 18-20, 22,24-26
X	WO 96 33276 A (HUMAN GENOME SCIENCES INC ;UNIV JOHNS HOPKINS (US)) 24 October 1996 (1996-10-24) page 35, line 1 -page 39, line 10 page 41, line 14 -page 45, line 30 page 77.390 -page 77.391; claims 1-20 ---	5-7,9, 15, 18-20, 22,24-26
A	US 5 599 693 A (HANSEN ERIC J ET AL) 4 February 1997 (1997-02-04) claims 1-12; figures 2,3 --- -/--	1-26

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 November 2000	'17. 11. 00

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van Klompenburg, W

2

Form PCT/ISA/210 (second sheet) (July 1992)

International Application No
PCT/EP 00/05852

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 607 846 A (BHUSHAN REVA ET AL) 4 March 1997 (1997-03-04) claims 1-8; examples C,D,E ---	1-26
A	MURPHY T F: "BRANHAMELLA CATARRHALIS: EPIDEMIOLOGY, SURFACE ANTIGENIC STRUCTURE, AND IMMUNE RESPONSE" MICROBIOLOGICAL REVIEWS,US,AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, DC, vol. 60, no. 2, July 1996 (1996-07), pages 267-279, XP000857203 ISSN: 0146-0749 page 271, column 2 -page 273 ---	1-26
A	HELMINEN M E ET AL: "HUMAN IMMUNE RESPONSE AGAINST OUTER MEMBRANE PROTEINS OF MORAXELLA (BRANHAMELLA) CATARRHALIS DETERMINED BY IMMUNOBLOTTING AND ENZYME IMMUNOASSAY" CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY,US,AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 2, no. 1, 1995, pages 35-39, XP002048788 ISSN: 1071-412X page 37, column 1 page 39, column 1 -----	1-26

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 00/05852

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9818323 A	07-05-1998	AU 5093398 A	22-05-1998
		BR 9712587 A	26-10-1999
		CN 1235513 A	17-11-1999
		EP 0973394 A	26-01-2000
		NO 991995 A	28-06-1999
		PL 333169 A	22-11-1999
		ZA 9709672 A	14-04-1999
		AU 5895498 A	29-06-1998
		BR 9714133 A	29-02-2000
		CN 1246799 A	08-03-2000
		EP 0964699 A	22-12-1999
		NO 992158 A	05-07-1999
		PL 333943 A	31-01-2000
		WO 9824475 A	11-06-1998
WO 9633276 A	24-10-1996	AU 5552396 A	07-11-1996
		CA 2218741 A	24-10-1996
		EP 0821737 A	04-02-1998
		JP 11501520 T	09-02-1999
US 5599693 A	04-02-1997	US 5552146 A	03-09-1996
		AT 140627 T	15-08-1996
		AU 666329 B	08-02-1996
		AU 2487892 A	16-03-1993
		CA 2115565 A	04-03-1993
		DE 69212495 D	29-08-1996
		DE 69212495 T	06-03-1997
		DK 612250 T	25-11-1996
		EP 0612250 A	31-08-1994
		ES 2092696 T	01-12-1996
		FI 940681 A	07-04-1994
		GR 3021423 T	31-01-1997
		JP 7501210 T	09-02-1995
		NO 940502 A	28-03-1994
		NO 2413 A	28-03-1994
		WO 9303761 A	04-03-1993
		US 5759813 A	02-06-1998
		US 5981213 A	09-11-1999
US 5607846 A	04-03-1997	AU 709984 B	09-09-1999
		AU 2396995 A	05-12-1995
		CA 2189971 A	23-11-1995
		EP 0759777 A	05-03-1997
		JP 10504444 T	06-05-1998
		NZ 284744 A	28-01-1999
		WO 9531215 A	23-11-1995
		US 5948412 A	07-09-1999

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 January 2001 (04.01.2001)

PCT

(10) International Publication Number
WO 01/00837 A1

(51) International Patent Classification[7]: C12N 15/31, C07K 14/21, A61K 39/02, 39/395, 48/00, G01N 33/569, C07K 16/12

(21) International Application Number: PCT/EP00/05852

(22) International Filing Date: 23 June 2000 (23.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9914945.2 25 June 1999 (25.06.1999) GB

(71) Applicant *(for all designated States except US)*: SMITHKLINE BEECHAM BIOLOGICALS S.A. [BE/BE]; Rue de l'Institut 89, B-1330 Rixensart (BE).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: THONNARD, Joelle [BE/BE]; SmithKline Beecham Biologicals S.A., Rue de l'Institut 89, B-1330 Rixensart (BE).

(74) Agents: PRIVETT, Kathryn, Louise et al.; SmithKline Beecham, Corporate Intellectual Property, Two New Horizons Court, Brentford, Middlesex TW8 9EP (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

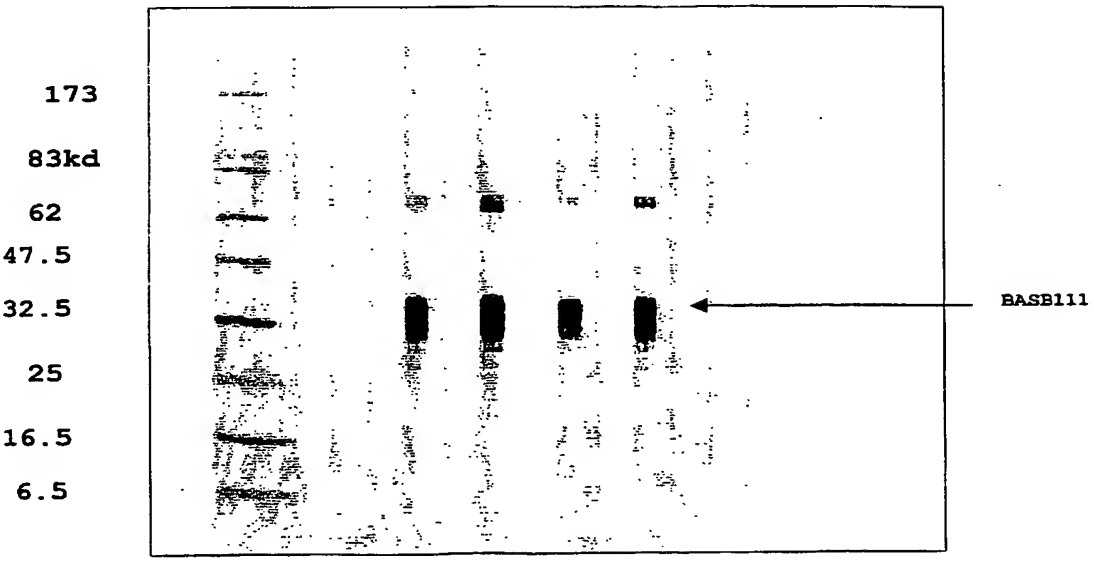
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

[Continued on next page]

(54) Title: BASB111 POLYPEPTIDE AND POLYNUCLEOTIDE FROM *MORAXELLA CATHARRHALIS*

Detection of BASB111 with rabbit antisera.



(57) Abstract: The invention provides BASB111 polypeptides and polynucleotides encoding BASB111 polypeptides and methods for producing such polypeptides by recombinant techniques. Also provided are diagnostic, prophylactic and therapeutic uses.

WO 01/00837 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

[redacted] national Application No
[redacted]./EP 00/05852

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/31 C07K14/21 A61K39/02 A61K39/395 A61K48/00
G01N33/569 C07K16/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C07K C12N A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 18323 A (ASTRA AB ;ALM RICHARD A (US); SMITH DOUGLAS (US)) 7 May 1998 (1998-05-07) SEQ ID NOs:19, 92 claims 1-65 ---	5-7,9, 15, 18-20, 22,24-26
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 November 2000	17. 11. 00

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van Klompenburg, W

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 607 846 A (BHUSHAN REVA ET AL) 4 March 1997 (1997-03-04) claims 1-8; examples C,D,E ---	1-26
A	MURPHY T F: "BRANHAMELLA CATARRHALIS: EPIDEMIOLOGY, SURFACE ANTIGENIC STRUCTURE, AND IMMUNE RESPONSE" MICROBIOLOGICAL REVIEWS,US,AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON, DC, vol. 60, no. 2, July 1996 (1996-07), pages 267-279, XP000857203 ISSN: 0146-0749 page 271, column 2 -page 273 ---	1-26
A	HELMINEN M E ET AL: "HUMAN IMMUNE RESPONSE AGAINST OUTER MEMBRANE PROTEINS OF MORAXELLA (BRANHAMELLA) CATARRHALIS DETERMINED BY IMMUNOBLOTTING AND ENZYME IMMUNOASSAY" CLINICAL AND DIAGNOSTIC LABORATORY IMMUNOLOGY,US,AMERICAN SOCIETY FOR MICROBIOLOGY, vol. 2, no. 1, 1995, pages 35-39, XP002048788 ISSN: 1071-412X page 37, column 1 page 39, column 1 -----	1-26

INTERNATIONAL SEARCH REPORT

[redacted]nation on patent family members

[redacted]national Application No
PCT/EP 00/05852

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9818323 A	07-05-1998	AU 5093398 A	22-05-1998
		BR 9712587 A	26-10-1999
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		EP 0973394 A	26-01-2000
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US 5599693 A	04-02-1997	US 5552146 A	03-09-1996
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SD/FB/BM45395		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/05852	23/06/2000	25/06/1999
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18/12/2000	18.09.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Mueller, F Telephone No. +49 89 2399 7722

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05852

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-64	as originally filed			
Claims, No.:				
1-28	as received on	17/08/2001	with letter of	16/08/2001
Drawings, sheets:				
2/3,3/3	as originally filed			
1/3	as received on	17/08/2001	with letter of	16/08/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25,28
	No:	Claims	5,7,15,16,17,20,21,22,24,26,27
Inventive step (IS)	Yes:	Claims	1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25,28
	No:	Claims	5,7,15,16,17,20,21,22,24,26,27
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re It m I

Basis of the report

The amendments filed with the letter of 16.08.2001, claims 1-28, fulfil the requirements of Article 34(2)(b).
The arguments given by the applicant on novelty and inventive step are taken into consideration. The presenting of a new copy of Figure 1 and the information sheet of the ATCC43617 is acknowledged.

Re Item V

Reasoned statement under Article 35 (2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.Reference is made to the following documents:

D1: WO 96 33276 A
D2: US-A-5 599 693
D3: US-A-5 607 846

The sequence alignment of the in D1 disclosed relevant sequence is designated as D4 and is annexed to the communication/report.

2. The subject-matter of claim 5 is not novel (Article 33 (2) PCT).
D1 describes the entire genome of Haemophilus influenza , isolated fragments and sequences thereof (see claims) and comprises a sequence which has a 70% homology in 838 nt overlap of the claimed and translated Seq Id 2 (nt652870-653680; pp. 77390-77391). The thereof translated protein sequence has a homology of 70% in a 276 aa overlap.
With the definition given in the present application, on page 6, lines 13-17, of the preferred polypeptide fragments, the in D1 disclosed sequence (nt 652870-653680) is falling within that given definition (19 homologue continuos aa). Thus novelty for claim 5 can not be acknowledged.
The new drafting of claim 5 still does not render the subject-matter of claim 5 novel over D1. D1 refers in claim 19 to an antibody which selectively binds to

fragments of Seq Id 1 and therefore D1 describes subject-matter which falls within the reading of present claim 5.

2.1 The subject-matter of dependent claim 7 and independent claims 15,16,17,20,21,22,24,26 and 27 is not novel (Article 33 (2) PCT).

D1 further describes isolated fragments of the Haemophilus influenza genome and vectors comprising them, a method of expressing polypeptides therefrom (see claims), antibodies selectively binding to those polypeptides (see p. 35, l.1-p.39, l.10), vaccine compositions and uses thereof (see page 41,l.14-page 45, line 30)
Thus novelty for claims 7,15,16,17,20,21,22,24,26 and 27 can not be acknowledged.

3. The subject-matter of independent claims 1,4,8,9,10,12,13,14,18,19,25,28 (Article 33 (2) PCT).
The same holds true for thereon dependent claims 2,3,6,11 and 23.

3.1 The subject-matter of claims 1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25 and 28 is inventive (Article 33 (3) PCT).
The prior art, equally represented by D2 and D3, describes nucleotide sequences from Morexalla catarrhalis and their use in immunological and diagnostic methods.
D2 describes the cloning and expression in host cell cultures (see col. 12-col.14, l.50) of a 30,80 and 100 kd outer membrane protein (OMP) of M. Catarrhalis (see examples 4,5,and 6 , col. 23-26). The expressed proteins are used for the preparation of vaccines, in immunoassays for detecting anti-OMP-reactive antibodies and therefore allowing the detection of M. catarrhalis infections (see col.18, line 15 -col. 20 ,l.56). D3 describes the preparation of OMP specific antibodies (see example 3, ,col. 21,l.20-col. 23, l.10) which are used in immunological assays and in passive immunization procedures (col. 11-lines 32-45).
D3 describes the use of the outer membrane protein E sequence of M. catarrhalis for constructing vectors (see col. 5 ,line 4-col. 10, line 6), the preparation of vaccines (see col. 16, line 5-col. 18 line 52) and primers and probes thereof

which are used in diagnostic assays (see col. 11 l.25-col.14,line 46).
The problem to be solved by the present application may therefore be regarded to provide a different nucleotide/polypeptide sequence of M. catarrhalis which is suitable for diagnostic and immunological methods.
A solution therefore is given in the present application by providing the sequence of the BASB111 polynucleotide.
As the prior art does not hint at the particular sequence Seq ID 2 or its use and as the BASB111 polynucleotide/polypeptide sequence is suitable for diagnostic, prophylactic, clinical and therapeutical use, see page 4, lines 21-25 and page 60, an inventive step can be acknowledged and the requirements of Article 33 (3) PCT are fulfilled.

4. The document WO9818323 is considered not to disclose subject-matter which is relevant in respect to novelty or inventive step. WO9818323 does not disclose fragment sequences of Seq ID2 which fulfil the definitions of fragments given on page 6, lines 13-17 in the present application.

Re Item VII
Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.

2. On page 61, lines 3-8, a reference is made to a deposit, ATCC43617, deposited on 21.06.1997 by Frosch and Kolle. Furthermore the it seems that the deposit is already described in Antimicrob. Agents Chemother. 21,506-508, 1982. Therefore it is not clear to which deposit it is refered in the present application. Thus the requirements of Article 5 PCT are not fulfilled.

Re Item VIII

Certain observations on th int rnational application

1. With the term in claim 9 "over the entire coding sequence" it seems that the polynucleotide sequence claimed comprises technical features which are not defined by Seq ID2 and therefore renders the subject-matter of claim 9 unclear (Article 6 PCT).

CLAIMS:

1. An isolated polypeptide comprising an amino acid sequence which has at least 85% identity to the amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2.

2. An isolated polypeptide as claimed in claim 1 in which the amino acid sequence has at least 95% identity to the amino acid sequence of SEQ ID NO:2.

3. The polypeptide as claimed in claim 1 comprising the amino acid sequence of SEQ ID NO:2.

4. An isolated polypeptide of SEQ ID NO:2.

5. An immunogenic fragment of the polypeptide as claimed in any one of claims 1 to 4 in which the immunogenic activity of said immunogenic fragment is substantially the same as the polypeptide of SEQ ID NO:2.

6. A polypeptide as claimed in any of claims 1 to 5 wherein said polypeptide is part of a larger fusion protein.

7. An isolated polynucleotide encoding a polypeptide as claimed in any of claims 1 to 6.

8. An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2; or a nucleotide sequence complementary to said isolated polynucleotide.

9. An isolated polynucleotide comprising a nucleotide sequence that has at least 85% identity to a nucleotide sequence encoding a polypeptide of SEQ ID NO:2 over the entire coding region; or a nucleotide sequence complementary to said isolated polynucleotide.

10. An isolated polynucleotide which comprises a nucleotide sequence which has at least 85% identity to that of SEQ ID NO:1 over the entire length of SEQ ID NO:1; or a nucleotide sequence complementary to said isolated polynucleotide.

11. The isolated polynucleotide as claimed in any one of claims 7 to 10 in which the identity is at least 95% to SEQ ID NO:1.

12. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2.

13. An isolated polynucleotide comprising the polynucleotide of SEQ ID NO:1.

14. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, obtainable by screening an appropriate library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1 or a fragment thereof.

15. An expression vector or a recombinant live microorganism comprising an isolated polynucleotide according to any one of claims 7 - 14.

16. A host cell comprising the expression vector of claim 15 or a membrane of said host cell expressing an isolated polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence of SEQ ID NO:2.

17. A process for producing a polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 comprising culturing a host cell of claim 16 under conditions sufficient for the production of said polypeptide and recovering the polypeptide from the culture medium.

18. A process for expressing a polynucleotide of any one of claims 7 – 14 comprising transforming a host cell with the expression vector comprising at least one of said polynucleotides and culturing said host cell under conditions sufficient for expression of any one of said polynucleotides.

19. A vaccine composition comprising an effective amount of the polypeptide of any one of claims 1 to 6 and a pharmaceutically acceptable carrier.

20. A vaccine composition comprising an effective amount of the polynucleotide of any one of claims 7 to 14 and a pharmaceutically effective carrier.

21. The vaccine composition according to either one of claims 19 or 20 wherein said composition comprises at least one other *Moraxella catarrhalis* antigen.

22. An antibody immunospecific for the polypeptide or immunological fragment as claimed in any one of claims 1 to 6.

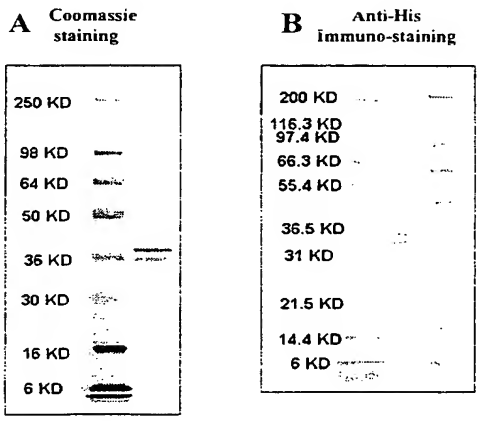
23. A method of diagnosing a *Moraxella* infection, comprising identifying a polypeptide as claimed in any one of claims 1 - 6, or an antibody that is immunospecific for said polypeptide, present within a biological sample from an animal suspected of having such an infection.

24. Use of a composition comprising an immunologically effective amount of a polypeptide as claimed in any one of claims 1 – 6 in the preparation of a medicament for use in generating an immune response in an animal.

25. Use of a composition comprising an immunologically effective amount of a polynucleotide as claimed in any one of claims 7 - 14 in the preparation of a medicament for use in generating an immune response in an animal.

26. A therapeutic composition useful in treating humans with *Moraxella catarrhalis* disease comprising at least one antibody directed against the polypeptide of claims 1 – 6 and a suitable pharmaceutical carrier.

Figure 1: Analysis of recombinant purified BASB111 separated through SDS-polyacrylamide gels and stained with Coomassie (A) and stained using anti-His immune reagent (B).



PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Peter John GIDDINGS
SMITHKLINE BEECHAM PLC
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	18.09.2001
Applicant's or agent's file reference SD/FB/BM45395	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/05852	23/06/2000	25/06/1999

Applicant
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Cleere, C Tel.+49 89 2399-7713

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SD/FB/BM45395		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/05852	23/06/2000	25/06/1999
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18/12/2000	18.09.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Mueller, F Telephone No. +49 89 2399 7722

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05852

I. Basis of th r port

1. With regard to the **lements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-64	as originally filed			
Claims, No.:				
1-28	as received on	17/08/2001	with letter of	16/08/2001
Drawings, sheets:				
2/3,3/3	as originally filed			
1/3	as received on	17/08/2001	with letter of	16/08/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25,28
	No:	Claims	5,7,15,16,17,20,21,22,24,26,27
Inventive step (IS)	Yes:	Claims	1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25,28
	No:	Claims	5,7,15,16,17,20,21,22,24,26,27
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations
   s e separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re It m I

Basis of the report

The amendments filed with the letter of 16.08.2001, claims 1-28, fulfil the requirements of Article 34(2)(b).
The arguments given by the applicant on novelty and inventive step are taken into consideration. The presenting of a new copy of Figure 1 and the information sheet of the ATCC43617 is acknowledged.

Re Item V

Reasoned statement under Article 35 (2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1.Reference is made to the following documents:

D1: WO 96 33276 A
D2: US-A-5 599 693
D3: US-A-5 607 846

The sequence alignment of the in D1 disclosed relevant sequence is designated as D4 and is annexed to the communication/report.

2. The subject-matter of claim 5 is not novel (Article 33 (2) PCT).
D1 describes the entire genome of Haemophilus influenza , isolated fragments and sequences thereof (see claims) and comprises a sequence which has a 70% homology in 838 nt overlap of the claimed and translated Seq Id 2 (nt652870-653680; pp. 77390-77391). The thereof translated protein sequence has a homology of 70% in a 276 aa overlap.
With the definition given in the present application, on page 6, lines 13-17, of the preferred polypeptide fragments, the in D1 disclosed sequence (nt 652870-653680) is falling within that given definition (19 homologue continuos aa). Thus novelty for claim 5 can not be acknowledged.
The new drafting of claim 5 still does not render the subject-matter of claim 5 novel over D1. D1 refers in claim 19 to an antibody which selectively binds to

fragments of Seq Id 1 and therefore D1 describes subject-matter which falls within the reading of present claim 5.

2.1 The subject-matter of dependent claim 7 and independent claims 15,16,17,20,21,22,24,26 and 27 is not novel (Article 33 (2) PCT).

D1 further describes isolated fragments of the Haemophilus influenza genome and vectors comprising them, a method of expressing polypeptides therefrom (see claims), antibodies selectively binding to those polypeptides (see p. 35, l.1-p.39, l.10), vaccine compositions and uses thereof (see page 41,l.14-page 45, line 30)
Thus novelty for claims 7,15,16,17,20,21,22,24,26 and 27 can not be acknowledged.

3. The subject-matter of independent claims 1,4,8,9,10,12,13,14,18,19,25,28 (Article 33 (2) PCT).
The same holds true for thereon dependent claims 2,3,6,11 and 23.

3.1 The subject-matter of claims 1,2,3,4,6,8,9,10,11,12,13,14,18,19,23,25 and 28 is inventive (Article 33 (3) PCT).
The prior art, equally represented by D2 and D3, describes nucleotide sequences from Morexalla catarrhalis and their use in immunological and diagnostic methods.
D2 describes the cloning and expression in host cell cultures (see col. 12-col.14, l.50) of a 30,80 and 100 kd outer membrane protein (OMP) of M. Catarrhalis (see examples 4,5,and 6 , col. 23-26). The expressed proteins are used for the preparation of vaccines, in immunoassays for detecting anti-OMP-reactive antibodies and therefore allowing the detection of M. catarrhalis infections (see col.18, line 15 -col. 20 ,l.56). D3 describes the preparation of OMP specific antibodies (see example 3, ,col. 21,l.20-col. 23, l.10) which are used in immunological assays and in passive immunization procedures (col. 11-lines 32-45).
D3 describes the use of the outer membrane protein E sequence of M. catarrhalis for constructing vectors (see col. 5 ,line 4-col. 10, line 6), the preparation of vaccines (see col. 16, line 5-col. 18 line 52) and primers and probes thereof

which are used in diagnostic assays (see col. 11 l.25-col.14,line 46).
The problem to be solved by the present application may therefore be regarded to provide a different nucleotide/polypeptide sequence of M. catarrhalis which is suitable for diagnostic and immunological methods.
A solution therefore is given in the present application by providing the sequence of the BASB111 polynucleotide.
As the prior art does not hint at the particular sequence Seq ID 2 or its use and as the BASB111 polynucleotide/polypeptide sequence is suitable for diagnostic, prophylactic, clinical and therapeutical use, see page 4, lines 21-25 and page 60, an inventive step can be acknowledged and the requirements of Article 33 (3) PCT are fulfilled.

4. The document WO9818323 is considered not to disclose subject-matter which is relevant in respect to novelty or inventive step. WO9818323 does not disclose fragment sequences of Seq ID2 which fulfil the definitions of fragments given on page 6, lines 13-17 in the present application.

R Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.

2. On page 61, lines 3-8, a reference is made to a deposit, ATCC43617, deposited on 21.06.1997 by Frosch and Kolle. Furthermore the it seems that the deposit is already described in Antimicrob. Agents Chemother. 21,506-508, 1982. Therefore it is not clear to which deposit it is refered in the present application. Thus the requirements of Article 5 PCT are not fulfilled.

Re Item VIII

Certain observations on th int rnational application

1. With the term in claim 9 "over the entire coding sequence" it seems that the polynucleotide sequence claimed comprises technical features which are not defined by Seq ID2 and therefore renders the subject-matter of claim 9 unclear (Article 6 PCT).

CLAIMS:

1. An isolated polypeptide comprising an amino acid sequence which has at least 85% identity to the amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2.

2. An isolated polypeptide as claimed in claim 1 in which the amino acid sequence has at least 95% identity to the amino acid sequence of SEQ ID NO:2.

3. The polypeptide as claimed in claim 1 comprising the amino acid sequence of SEQ ID NO:2.

4. An isolated polypeptide of SEQ ID NO:2.

5. An isolated immunogenic fragment of the polypeptide as claimed in any one of claims 1 to 4 which fragment (if necessary when coupled to a carrier) is capable of raising an immune response which recognises the polypeptide of SEQ ID NO:2.

6. A polypeptide as claimed in any of claims 1 to 5 wherein said polypeptide is part of a larger fusion protein.

7. An isolated polynucleotide encoding a polypeptide as claimed in any of claims 1 to 6.

8. An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2; or a nucleotide sequence complementary to said isolated polynucleotide.

9. An isolated polynucleotide comprising a nucleotide sequence that has at least 85% identity to a nucleotide sequence encoding a polypeptide of SEQ ID NO:2 over the entire coding region; or a nucleotide sequence complementary to said isolated polynucleotide.

10. An isolated polynucleotide which comprises a nucleotide sequence which has at least 85% identity to that of SEQ ID NO:1 over the entire length of SEQ ID NO:1; or a nucleotide sequence complementary to said isolated polynucleotide.

11. The isolated polynucleotide as claimed in any one of claims 7 to 10 in which the identity is at least 95% to SEQ ID NO:1.

12. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2.

13. An isolated polynucleotide comprising the polynucleotide of SEQ ID NO:1.

14. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, obtainable by screening an appropriate library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1 or a fragment thereof.

15. An expression vector comprising an isolated polynucleotide according to any one of claims 7 - 14.

16. A recombinant live microorganism comprising an expression vector according to claim 15.

17. A host cell comprising the expression vector of claim 15.

18. A membrane of the host cell according to claim 17 expressing an isolated polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence of SEQ ID NO:2.

19. A process for producing a polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 comprising culturing a host cell of claim 17 under conditions sufficient for the production of said polypeptide and recovering the polypeptide from the culture medium.

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20. A process for expressing a polynucleotide of any one of claims 7 – 14 comprising transforming a host cell with the expression vector comprising at least one of said polynucleotides and culturing said host cell under conditions sufficient for expression of any one of said polynucleotides.

21. A vaccine composition comprising an effective amount of the polypeptide of any one of claims 1 to 6 and a pharmaceutically acceptable carrier.

22. A vaccine composition comprising an effective amount of the polynucleotide of any one of claims 7 to 14 and a pharmaceutically effective carrier.

23. The vaccine composition according to either one of claims 21 or 22 wherein said composition comprises at least one other *Moraxella catarrhalis* antigen.

24. An antibody generated against the polypeptide or immunological fragment as claimed in any one of claims 1 to 6.

25. A method of diagnosing a *Moraxella* infection, comprising identifying a polypeptide as claimed in any one of claims 1 - 6, or an antibody that is immunospecific for said polypeptide, present within a biological sample from an animal suspected of having such an infection.

26. Use of a composition comprising an immunologically effective amount of a polypeptide as claimed in any one of claims 1 – 6 in the preparation of a medicament for use in generating an immune response in an animal.

27. Use of a composition comprising an immunologically effective amount of a polynucleotide as claimed in any one of claims 7 - 14 in the preparation of a medicament for use in generating an immune response in an animal.

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28. A therapeutic composition useful in treating humans with *Moraxella catarrhalis* disease comprising at least one antibody directed against the polypeptide of claims 1 – 6 and a suitable pharmaceutical carrier.

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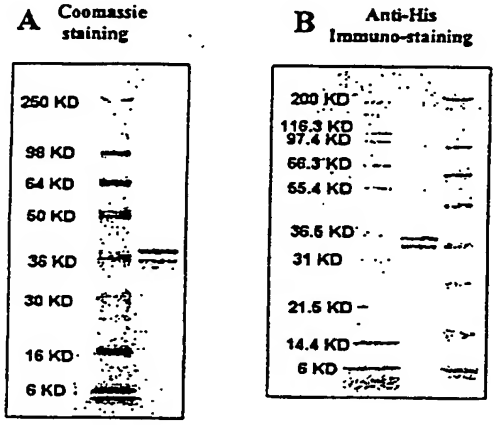
Figure 1: Analysis of recombinant purified BASB111 separated through SDS-polyacrylamide gels and stained with Coomassie (A) and stained using anti-His immune reagent (B).



AMENDED SHEET